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IS 12855 (1989): Dental Materials - Root Canal Sealing Materials [MHD 8: Dentistry]

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Indian Standard

DENTAL MATERIALS—ROOT CANAL SEALING MATERIALS—SPECIFICATION

भारतीय मानक

दंत सामग्री — जड़ के खोखले स्थान में भराई सामग्री — विशिष्टि

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NEW DELHI 110002

July 1990

Price Group 2

Dental Materials Sectional Committee, CDC 52

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards on 24 January 1989, after the draft finalized by the Dental Materials Sectional Committee had been approved by the Chemical Division Council.

Ever since endodontics first became a special area of dental practice, materials for endodontic use have been continually developed. However, until now the evaluation of these materials has been largely based on empirical evidence of usefulness. It is hoped that this standard will be found useful in assessing new materials according to standard recognized criteria.

This standard is based on ISO 6876 : 1986 'Dental root canal sealing materials', issued by the International Organization for Standardization (ISO).

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

DENTAL MATERIALS — ROOT CANAL SEALING MATERIALS — SPECIFICATION

1 SCOPE

1.1 This standard specifies the requirements for materials used for permanent obturation of the root canal with or without the aid of obturating points.

1.2 This standard covers only the materials intended for orthograde (root filling inserted from coronal aspect) use.

2 REFERENCES

2.1 The following Indian Standards are necessary adjuncts to this standard:

IS No.	*Title*
1070 : 1977	Water for general laboratory use (*second revision*)
12572 (Part 10) : 1989	Guide for evaluation of medical devices for biological hazards: Part 10 Methods of tests for dental materials

3 CLASSIFICATION

3.1 The root canal sealing materials covered by this standard shall be classified into the following types:

a) *Type* 1 (*Setting Materials*)

These are materials which set within 72 hours of commencement of mixing.

b) *Type* 2 (*Non-setting Materials*)

4 REQUIREMENTS

4.1 Component Ingredients

4.1.1 The component ingredients of the sealing materials shall be sterile and free from extraneous matter.

4.1.2 The purity and sterility of the ingredients shall comply with the relevant requirements of the Indian pharmacopoeia or such requirements as are applicable to purity and sterility of pharmaceutical products.

4.1.3 The ingredients shall, when used in accordance with the manufacturer's instructions, form a material which complies with the requirements of this standard.

4.2 Freedom from Toxicity

The material shall not cause any irreversible damage when in contact with the oral tissues [reference may be made to IS 12572 (Part 10) : 1989, which gives guidance on the biological evaluation of dental materials].

4.3 Flow

The flow of the material, when determined in accordance with **7.3** shall produce a disc with a diameter of not less than 20 mm.

4.4 Working Time

The working time for Type 1 materials having a working time of less than 30 minutes when determined by the method given in **7.4** shall be within ±10 percent of that stated by the manufacturer [*see* **5.1** (e)].

4.5 Setting Time

The setting time for Type 1 materials determined by the method given in **7.5** shall be within ±10 percent of that stated by the manufacturer [*see* **5.1** (e)].

4.5.1 For materials have a setting time greater than 30 minutes for which the manufacturer quotes a range of time, the setting time measured shall be within the specified range.

4.6 Film Thickness

The film thickness for material intended for use with obturating points, shall not be more than 50 μm when tested in accordance with **7.6**.

4.7 Radio-opacity

The material when tested in accordance with **7.7** shall have a radio-opacity equivalent of not less than 3 mm of aluminium.

4.8 Solubility and Disintegration

The solubility of the material when determined in accordance with **7.8** shall not exceed by 3 percent of mass nor shall subsequently show evidence of disintegration.

5 MANUFACTURER'S INSTRUCTIONS

5.1 Each package shall be provided with the manufacturer's instructions, which shall include the following:

a) Instructions for use of the material, including, where applicable, the method of mixing and component mixing ratio;

b) The recommended method for sterilization, if possible or necessary;

c) Principal components and active ingredients of material(s);

d) Recommended conditions of storage;

e) The working time (if less than 30 minutes) and the setting time of the material — if the material is of the non-setting variety this should be stated; if a precise setting time cannot be determined but it exceeds 30 minutes, a range may be quoted;

f) Indications for clinical use, including whether the material is manufactured for use with obturating points — if the material can cause staining of the tooth, this should be stated together with any precautions necessary to minimize this effect.

6 SAMPLING

6.1 The sample shall consist of one or more retail packages from the same batch, containing sufficient material to carry out the specified tests, plus an allowance for repeats, if necessary.

7 TEST METHODS

7.1 Test Conditions

Unless otherwise stated by the manufacturer, all tests shall be carried out at 27 ± 2°C and at a relative humidity 65 ± 5 percent.

7.2 Preparation of Material for Testing

The material shall be manipulated in accordance with the manufacturer's instructions.

7.3 Flow

7.3.1 *Apparatus*

7.3.1.1 *Two glass plates*, having minimum dimensions of 30 mm × 30 mm, and approximately 5 mm thick.

7.3.1.2 *Loading device*, to apply a load of 2·5 kg.

7.3.1.3 *Graduated glass delivery tube*, designed to deliver 0·075 ± 0·005 ml of mixed material.

7.3.2 *Procedure*

Using the glass delivery tube (**7.3.1.3**), deposit 0·075 ml of the material mixed in accordance with the manufacturer's instructions, on to one of the glass plates (**7.3.1.1**). After 180 ± 5 seconds from the start of mixing, place the other glass plate centrally on the material and carefully apply, by means of the loading device (**7.3.1.2**), the 2·5 kg load. After 10 minutes from the start of mixing, remove the load and measure the major and minor diameters of the disc. Record the mean of the major and minor diameters. If the diameters differ from each other by more than 1 mm, repeat the test.

7.3.3 *Calculation and Expression of Results*

Carry out three determinations, calculate the mean result and record it, to the nearest millimetre, as the flow value.

7.4 Working Time

This test applies only to Type 1 material having a working time of less than 30 minutes (*see* **4.4**).

7.4.1 *Apparatus*

The apparatus specified in **7.3.1** shall be used.

7.4.2 *Procedure*

Using the glass delivery tube (**7.3.1.3**), deposit 0·075 ml of the material, mixed in accordance with the manufacturer's instructions, onto one of the glass plates (**7.3.1.1**). After 210 ± 5 seconds from the start of mixing, place the other glass plate centrally on the material and carefully apply, by means of the loading device (**7.3.1.2**), the 2·5 kg load. Apply the load for 7 minutes, then remove it and measure the major and minor diameters of the disc. Record the mean of the major and minor diameters.

Repeat the test with newly mixed material, applying the load and increasing intervals of time after the start of mixing until the diameter has decreased by 10 percent from the flow value (*see* **7.3.3**).

7.4.3 *Calculation and Expression of Results*

Carry out three determinations, calculate the mean result and record it, to the nearest 30 seconds, as the working time of the material.

7.5 Setting Time

This test applies only to Type 1 materials (*see* **4.5**).

7.5.1 *Apparatus*

7.5.1.1 *Cabinet*, capable of being maintained at a temperature of 37 ± 1°C and a relative humidity of not less than 95 percent.

7.5.1.2 *Gilmore-type metric indenter*, having a mass of 100 ± 0·5 g and a flat end of diameter 2 ± 0·1 mm. The needle tip shall be cylindrical over a length of at least 5 mm. The end of the needle shall be plane and at right angles to the longitudinal axis and shall be kept clean.

7.5.1.3 *Stainless steel ring mould*, having an internal diameter of 10 mm and a height of 2 mm.

7.5.1.4 *Metal block*, having minimum dimensions of 8 mm × 20 mm × 10 mm.

7.5.1.5 *Flat glass plate*, approximately 1 mm thick.

NOTE — A microscope slide is suitable.

7.5.2 *Procedure*

Place the mould (**7.5.1.3**) on the glass plate (**7.5.1.5**) and fill it to a level surface with material mixed in accordance with the manufacturer's instructions. After 120 ± 10 seconds from the start of mixing, place this assembly on the metal block (**7.5.1.4**) maintained at 37 ± 1°C in the cabinet (**7.5.1.1**).

When the setting time stated by the manufacturer approaches, carefully lower the Gilmore-type needle (**7.5.1.2**) vertically onto the horizontal surface of the material. Repeat this operation until indentations cease to be visible and then record the time from the start of mixing.

7.5.3 *Calculation and Expression of Results*

Carry out three determinations, calculate the mean result and record it as the setting time.

7.6 Film Thickness

7.6.1 *Apparatus*

7.6.1.1 *Two optically flat circular glass plates*, having a minimum uniform thickness of 5 mm and a contact surface area of approximately 200 mm^2.

7.6.1.2 *Loading device*, to apply a load of 15 kg.

7.6.1.3 Micrometer or similar measuring instrument, accurate to 1 µm.

7.6.2 *Procedure*

Measure the combined thickness of the two glass plates (**7.6.1.1**) in contact to an accuracy of 1 µm. Deposit a portion of material, mixed in accordance with the manufacturer's instructions, onto the centre of one of the glass plates. Place the other glass plate centrally on the material. After 180 ± 10 seconds from the start of mixing, carefully apply, by means of the loading device (**7.6.1.2**), a load of 15 kg vertically on the top plate. Ensure that the material completely fills the area between the glass plates. After 10 minutes from the start of mixing, measure the thickness of the two glass plates and the film of material using the micrometer (**7.6.1.3**).

7.6.3 *Calculation and Expression of Results*

Calculate the thickness of the film by determining the difference in thickness of the plates with and without the material. Carry out three determinations, calculate the mean result and record it, to the nearest 5 µm, as the film thickness.

7.7 Radio-opacity

7.7.1 *Apparatus*

7.7.1.1 *Stainless steel ring mould*, having an internal diameter of 10 mm and a height of 1 mm, together with covers, made of either plastics, paper or other radiolucent material.

7.7.1.2 *Dental X-ray unit*, capable of being operated at 65 kV.

7.7.1.3 *Dental X-ray occlusal film*, of suitable speed, *developing solution* and *fixer*.

7.7.1.4 *Aluminium step wedge*, 50 mm × 20 mm, having a thickness range from 1 to 10 mm in steps of 1 mm, and made of at least 99·5 percent pure aluminium.

7.7.1.5 *Photographic densitometer*

7.7.2 *Procedure*

Place the material, mixed in accordance with manufacturer's instructions in the mould (**7.7.1.1**) and press the covers on the top and bottom to make a specimen 1 mm thick. Position the specimen in the centre of the X-ray film (**7.7.1.3**) adjacent to the aluminium step wedge (**7.7.1.4**). If a cover is used, place an equivalent cover under the step wedge. Irradiate the specimen, step wedge and film at a target film distance of approximately 300 mm for such a time that the exposed and processed film under the 1 mm thick section of the step wedge has a photographic density in the region of 1·5 to 2·5, including base and fog. After developing, fixing and drying the exposed film, measure the photographic, density of the radiographic image of the specimen, each of the steps of the step wedge and the totally exposed film, using the densitometer (**7.7.1.5**).

7.7.3 *Expression of Results*

By comparison with the image of the step wedge, determine the thickness of aluminium equivalent to the specimen. Record this to the nearest

0·1 mm. Carry out three determinations, calculate the mean result and record it as the radio-opacity value.

7.8 Solubility and Disintegration

7.8.1 *Apparatus and Materials*

7.8.1.1 *Two split ring moulds*, having an internal diameter of 20 mm and a height of 1·5 mm.

7.8.1.2 *Four polished flat glass plates*, having dimensions larger than the maximum dimensions of the split ring moulds.

7.8.1.3 *Sheets of impervious plastics*, such as polyethylene.

7.8.1.4 *Glass petri dish*, having a diameter of approximately 90 mm, with a minimum volume of 50 ml and of known mass.

7.8.1.5 *Cabinet*, capable of being maintained at a temperature of 37 ± 1°C and a relative humidity of not less than 95 percent.

7.8.1.6 *Water*, complying with IS 1070 : 1977.

7.8.1.7 *Desiccator*, containing phosphorous pentoxide or other suitable desiccant.

7.8.2 *Procedure*

Place a mould (**7.8.1.1**) on a glass plate (**7.8.1.2**), the net masses of which are known to the nearest 0·001 g and fill to slight excess with mixed (if necessary) material. Press another glass plate faced with a sheet of plastics (**7.8.1.3**) on top of the material and carefully remove to leave a flat, uniform surface.

If the material is of Type 1, place the filled mould in the cabinet (**7.8.1.5**) for a period of time 50 percent longer than the setting time stated by the manufacturer [*see* **5**(e)].

Determine the mass of material to the nearest 0·001 g.

Place two such specimens in the petri dish (**7.8.1.4**) such that the surfaces do not touch and the material remains undisturbed in the mould. Add 50 ± 1 ml of water (**7.8.1.6**) and cover the dish. Store the petri dish and contents at 37 ± 1°C for 24 hours and then remove the specimens. Wash the specimens with a little of water allowing the washings to drain back into the petri dish. Discard the specimens.

Evaporate the water from the dish without boiling and dry the dish to constant mass at 150°C, cooling the dish in the desiccator (**7.8.1.7**) to room temperature before each weighing (accurate to the nearest 0·001 g).

7.8.3 *Calculation and Expression of Results*

Carry out two tests for each material. Record the mean difference between the original mass of the petri dish and its final mass, to the nearest 0·001 g, as the amount of material removed from the specimens. Record this difference in mass, calculated as a percentage of the original combined mass of the two specimens reported to the nearest 0·1 percent as the solubility of the material.

8 PACKAGING

8.1 The components shall be supplied in securely sealed containers, made from materials which do not react with or permit contamination of the contents.

9 MARKING

9.1 Each package and/or container within the package shall be clearly and legibly marked with the following particulars:

a) Name and/or trade-mark of the manufacturer;

b) Name of the product;

c) Number or code which shall refer to the manufacturer's record and date of manufacture for the particular batch of the material(s);

d) Minimum mass, in grams, of the powder or pastes and the minimum net volume, in millilitres, of the liquid, if included; and

e) Recommended conditions of storage and, if applicable, expiry date when stored under those coditions.

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